PATENT COOPERATION TREATY

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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference A02 P 2022 P	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/SE 03/01297	International filing date *(day/month/year)* 19.08.2003	Priority date *(day/month/year)* 27.09.2002
International Patent Classification (IPC) or both national classification and IPC A61N1/365		
Applicant ST. JUDE MEDICAL AB et al		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 5 sheets, including this cover sheet.

   ☐ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of sheets.

3. This report contains indications relating to the following items:

   I ☒ Basis of the opinion
   II ☐ Priority
   III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   IV ☐ Lack of unity of invention
   V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   VI ☐ Certain documents cited
   VII ☐ Certain defects in the international application
   VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
19.11.2003	01.09.2004
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized Officer Schoeffmann, H Telephone No. +49 89 2399-2625

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/SE 03/01297

I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:

Description, Pages

1-16 as published

Claims, Numbers

1-13 as published

Drawings, Sheets

1/3-3/3 as published

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

   These elements were available or furnished to this Authority in the following language: , which is:

   ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).

   ☐ the language of publication of the international application (under Rule 48.3(b)).

   ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

   ☐ contained in the international application in written form.

   ☐ filed together with the international application in computer readable form.

   ☐ furnished subsequently to this Authority in written form.

   ☐ furnished subsequently to this Authority in computer readable form.

   ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

   ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

   ☐ the description, pages:

   ☐ the claims, Nos.:

   ☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

   (Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

   ☐ the entire international application,

   ☒ claims Nos. 4-8

   because:

   ☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (specify):

   ☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. are so unclear that no meaningful opinion could be formed *(specify)*:

   ☒ the claims, or said claims Nos. 4-8 are so inadequately supported by the description that no meaningful opinion could be formed.

   ☐ no international search report has been established for the said claims Nos.

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

   ☐ the written form has not been furnished or does not comply with the Standard.

   ☐ the computer readable form has not been furnished or does not comply with the Standard.

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	3,9
	No:	Claims	1,2,10-13
Inventive step (IS)	Yes:	Claims	9
	No:	Claims	3
Industrial applicability (IA)	Yes:	Claims	1-3,9-13
	No:	Claims	

2. Citations and explanations

   see separate sheet

Concerning Sections III and V:

1. Reference is made to the following document:

   D1... US-A-4 869 252

2. Claim 1 is so vaguely drafted that it reads onto document D1. Document D1 discloses an implantable cardioverter defibrillator including an autocapture mode of operation, the D1 system comprises

   - a pulse generator (cf. D1, fig.2 (36))
   - a defibrillation unit (cf. fig.1, (17))
   - sensing circuitry for sensing heart activity (fig.2, (37))
   - control unit (fig.1, (16)) for controlling timing and energy of the pacing pulses and cardioversion shocks,
   - a first operating mode being the autocapture mode of operation (cf. fig.4, of D1, blocks (87,88) and col.3, lines 21-24),
   - a second mode of operation in which pacing pulses according to predetermined pacing pulse settings are delivered (fig.4, block 81: pacing amplitude set to 4V),
   - the control unit is arranged for switching the system from said first operating mode into said second operating mode following delivery of a cardioversion shock (cf. fig.4: after defibrillation (block 93) the ICD switches into the second mode (block 81) of pacing at according to predetermined pacing settings) .

   Accordingly, the subject-matter of claim 1 lacks novelty and the requirement of Art.33(2) PCT is not met.

3. D1 also discloses the additional features as defined in current dependent claims 2,10-13 (Art.33(2) PCT not met):

   claim 2: mode switching after a predetermined time interval, see fig.4 of D1, block (93);
   claims 10-13: see figs.1,2 of D1

4. D1 does not mention the absolute time duration for the post defibrillation time out,

it appears however that suitable time intervals will be found by the skilled person by routine trial and error. Therefore, claim 3 is considered to lack an inventive step so that the requirement of Art.33(3) PCT is not met.

5. Claims 4 to 6 are indefinite with regard to the characteristic to be evaluated for extending PSD. As the sole parameter that has been disclosed is the amplitude of heart activity, these claims are not supported in the their entire scope by the disclosure of the application. An objection under Art.6 PCT thus arises. As claims 7 and 8 depend directly from the unsupported claims 4-6 no statement with respect to Art.33 PCT is feasible.

6. Claim 9 which defines the missing essential feature thus may be considered to meet the requirements of Art.6 PCT. As no available prior art document teaches to delay resumption of the autocapture mode after shock delivery as long as the heart signal amplitude remains below a certain threshold claim 9 could also be considered to meet the requirements of Art.33 PCT. The said feature avoids false determinations of pacing pulse amplitudes caused by an increased capture threshold immediately after shock.

7. For completeness, the independent claim 1 should have been drafted in the correct two-part form with respect to D1 (Rule 6.3(b)(i),(ii) PCT) and D1 should have been acknowledged in the description (Rule 5.1(a)(ii) PCT).